

FEB 16 2000

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oncology systems

K992751

**Premarket Notification [510K] Summary
as required by 21 CFR 807.92**

Date Summary was prepared:

August 12, 1999

Submitter's Name:

Varian Medical Systems
3100 Hansen Way M/S H-055
Palo Alto, CA 94304

Contact Person:

Linda S. Nash
Regulatory Affairs and Quality Assurance Manager
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Device Name:

Somavision 6.0

Classification Name:

System, Simulation, Radiation Therapy

Predicate Device:

General Electric Advantage Sim

age 1 of 2

Product Description:

Somavision is an advanced treatment planning preparation workstation with 3D image capabilities.

Intended Use:

The Varian SomaVision 6.0 device is a CT simulation system used for diagnostic image analysis, contouring & segmentation, geometrical planning and plan review

Technological Characteristics:

See the attached “Specification Comparison Chart”, Tab F.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Linda S. Nash
Regulatory Affairs and Quality Assurance Manager
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, CA 94304-1129

Re: K992751
SomaVision 6.0 (Radiation Therapy
Simulation Software System
Dated: November 18, 1999
Received: November 19, 1999
Regulatory class: II
21 CFR 892.5840/Procode: 90 KPQ

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): _____

Device Name: Somavision 6.0

Indications for Use:

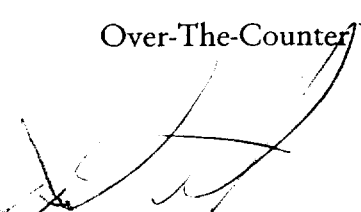
Somavision is an advanced treatment planning preparation workstation for the physician and include high quality 3-D image capabilities. As part of the Varis Vision System, Somavision integrates treatment planning in the overall therapy process, while taking advantage of the Varian Vision database.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR
(per 21 CFR 801.109)

Over-The-Counter Use _____



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992751

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